Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DANIELA SANTOLI,
GIOVANNI ROVERA, and
ALESSANDRA CESANO

Appeal No. 2001-2411
Application No. 08/879,422

ON BRIEF

Before WINTERS, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 3, and 5-14, all of the claims in the application. Claim 1 is representative and reads as follows:

1. A method of treating cancer in a mammalian patient, comprising the step of:

   administering to a mammalian cancer patient with a functional immune system an effective amount of TALL-104 cells ATCC Accession No. CRL11386, which cells have been modified by stimulation in vitro by treatment with a cytokine and gamma irradiation at a dose suitable to irreversibly arrest cell proliferation

> but not interfere with the cytotoxic activity of the cells, said modified cells characterized by irreversibly arrested cell proliferation and non-MHC restricted cytotoxic activity, in the absence of an immunosuppressive agent.

The examiner does not rely on any references.

Claims 1, 3, and 5-14 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

Claims 1, 3, and 5-14 also stand rejected under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description and an enabling disclosure in the specification.

We reverse all three rejections.

Background

The specification discloses that "[a]doptive transfer therapy for the treatment of cancer has been described. One such method makes use of a lethally irradiated human T cell line (TALL-104). . . . To date, the use of this TALL-104 cell line in such adoptive transfer has been described as requiring an immunosuppressed patient." Pages 1-2. The specification cites several publications as describing the use of TALL-104 cells to treat cancer in both immunodeficient animal models and immunocompetent animals having spontaneously arising cancers; in the latter experiments, the immunosuppressive agent cyclosporin A was administered to avoid rejection of the allogeneic TALL-104 cells. See page 2. The specification discloses "a method of treating cancer, and particularly, for preventing recurrence of cancer. This method involves the step of administering an effective amount of modified TALL-104 cells

to a mammalian patient in the absence of an immunosuppressive agent." Id., pages 2-3.

Discussion

The examiner rejected all of the claims for indefiniteness, inadequate written description, and nonenablement. Each of the rejections is based on the same claim limitation: the limitation that the TALL-104 cells are administered to a cancer patient "with a functional immune system." In the examiner's view, this limitation renders the claims indefinite, inadequately described, and nonenabled. We disagree.

1. Claim construction

Claim language must be interpreted in light of the claim as a whole, the specification of which the claim is a part, and the prosecution history. See General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1275, 23 USPQ2d 1839, 1840 (Fed. Cir. 1992) ("[E]ach claim is an entity which must be considered as a whole.") (emphasis in original); Renishaw plc v. Marposs Societa per Azioni, 158 F.3d 1243, 1248, 48 USPQ2d 1117, 1120 (Fed. Cir. 1998) ("[A] claim must be read in view of the specification of which it is a part."); id. at 1249 n.3, 48 USPQ2d 1117, 1121 n.3 ("Likewise, any interpretation that is provided or disavowed in the prosecution history also shapes the claim scope.").

In addition, "[i]t is axiomatic that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art."

In re Sneed, 710 F.2d 1544,1548, 218 USPQ 385, 388 (Fed. Cir. 1983). Words in a claim are given their ordinary definition unless they are clearly defined otherwise in the specification. See Optical Disc Corp. v. Del Mar Avionics, 208 F.3d 1324, 1334, 54 USPQ2d 1289, 1295 (Fed. Cir. 2000) ("Without evidence in the patent specification of an express intent to impart a novel meaning to a claim term, the term takes on its ordinary meaning.").

The claim language at issue in this case is the limitation that the patient has "a functional immune system." This phrase is found in the following context: "administering to a mammalian cancer patient with a functional immune system an effective amount of TALL-104 cells . . . in the absence of an immunosuppressive agent." Thus, in the context of the claim as a whole, a "functional immune system" is an immune system that would be suppressed by an immunosuppressive agent, i.e., an immune system that would mount an immune response to a foreign antigen unless such a response was pharmacologically suppressed.

The specification sheds further light on what is meant by a "functional immune system." The specification distinguishes between "immunodeficient" and "immunocompetent" murine models. See page 2. The immunodeficient murine model used in the cited references is the SCID (severe combined immunodeficient) mouse.[1] SCID mice "lack functional T cells and B cells." See

[1] See Cesano et al., "Reversal of acute myelogenous leukemia in humanized SCID mice using a novel adoptive transfer approach," Journal of Clinical Investigation, Vol. 94, pp. 1076-1084 (1994). This reference is cited in the specification (page 2) and was made of record in Paper No. 8, filed Nov. 10, 1998.

McCune, page 1633.[2] As a result, SCID mice "have severe combined immunodeficiency, an inability to mount an effective cellular or humoral immune response to foreign antigens." Id.

In contrast, when immunocompetent mice were used, their immune systems reacted to the allogeneic TALL-104 cells and eventually rejected them.[3] The specification discloses that the treatment of these mice, as well as treatment of dogs having spontaneously arising tumors, included administration of cyclosporin A "to avoid rejection of the allogeneic TALL-104 effector cells." Page 2. Thus, the specification suggests that patients having a functional immune system, a.k.a. immunocompetent patients, are those having an immune system that would be expected to mount an immune response when administered allogeneic cells.

Finally, the prosecution history shows that the "functional immune system" limitation was added in order to distinguish the claimed process from prior art disclosing administration of TALL-104 cells to immunodeficient animal models. In Paper No. 17 (mailed Oct. 28, 1999), the examiner rejected claims reciting administration of TALL-104 cells "in the absence of an immunosuppressive agent" as anticipated by references disclosing administration of TALL-104 cells to immunodeficient SCID mice. See page 2. In response, Appellants amended the

[2] McCune et al., "The SCID-hu mouse: Murine model for the analysis of human hematolymphoid differentiation and function, Science, Vol. 241, pp. 1632-1639 (1988) (exhibit A attached to the Appeal Brief).
[3] See Cesano et al., "Antitumor efficacy of a human major histocompatibility complex nonrestricted cytotoxic T-cell line (TALL-104) in immunocompetent mice bearing syngeneic leukemia," Cancer Research, Vol. 56, pp. 4444-4452 (1996). This reference is cited in the specification (page 2) and was made of record in Paper No. 8, filed Nov. 10, 1998.

claims to require that the treated patient have a "functional immune system." See Paper No. 18 (filed Jan. 28, 2000), page 2. Appellants argued that "SCID mice do not have a working immune system. Since the mice are immunodeficient, without B or T lymphocytes, . . . [they] do not need immunosuppressive treatment prior to receiving foreign cells, such as TALL-104 cells." Id., page 3.

Finally, in the Appeal Brief, Appellants argue that "[t]he term 'functional immune system' does not mean to the person of skill in the art that the patient's immune system is perfect, but simply that it is operational, i.e., that humoral and/or cellular immune responses are functioning in the patient." Page 4. Appellants have cited two dictionaries as defining "functional" to mean "capable of performing; operative,"[4] or "performing or able to perform a function."[5] See the Appeal Brief, pages 9-10.

On the basis of the record, including the claim as a whole, the specification, and the prosecution history, we agree with Appellants' interpretation of the claim language. We construe a "functional immune system" to be an immune system that can mount an effective humoral and/or cellular immune response to foreign antigens. In other words, a patient with a functional immune system is simply a patient who is not immunodeficient (e.g., not a SCID mouse). A functional immune system is not limited to those immune systems that work perfectly or that respond with 100% effectiveness to every potential

[4] The American Heritage Dictionary of the English Language, 3rd ed. (1996) (exhibit F attached to the Appeal Brief).

antigen that might be present. As discussed below, this interpretation of the claim language effectively resolves all of the issues on appeal.

2. Definiteness

"The definiteness of the language employed must be analyzed—not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). The examiner rejected the claims as indefinite "in the recitation of 'with a functional immune system' because it is unclear what this phrase means." Paper No. 19, mailed April 19, 2000, page 4. The examiner concluded it was unclear what specific immune functions or immune cells were intended, and what level of immune function was required by the term "functional." See id.

As discussed above, we have construed "a functional immune system" to mean an immune system that mounts a humoral and/or cellular immune response to foreign antigens. Thus, we do not agree with the examiner that the claim language is indefinite, i.e., that a person skilled in the art would not understand the bounds of the claims when read in light of the specification. See Miles Laboratories Inc. v. Shandon Inc., 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993) ("The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the

[5] Webster's New World Dictionary, 3rd College Edition (1991) (exhibit H attached to the Appeal Brief).

specification."). The rejection under 35 U.S.C. § 112, second paragraph, is reversed.

3. Written description

"In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue." Purdue Pharma L.P. v. Faulding, Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000). Nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. See id.

The examiner rejected the claims as inadequately described because "[t]here is no support in the specification as originally filed for the recitation of 'with a functional immune system' in claim 1." Paper No. 19, mailed April 19, 2000, page 2. The examiner noted that none of the passages pointed to by Appellants recites the claim limitation of a patient with a functional immune system. See id., pages 2-3.

We find that the specification adequately describes the claimed method. As discussed above, the record as a whole makes clear that a patient with a functional immune system is simply an immunocompetent, as opposed to immunodeficient, patient. The specification shows that Appellants were in possession of the claimed method of treating a mammalian cancer patient having a functional immune system, in the absence of an immunosuppressive agent. See, e.g., Example 1, which is headed "Induction of specific anti-tumor immunity by TALL-104 cells in immunocompetent mice bearing syngeneic leukemia."

Pages 11-12 (emphasis added). See also Example 3, which compares the results of treating dogs having malignant histiocytosis with TALL-104 cells, either in the presence or absence of cyclosporin A (pages 16-25).

We therefore find that the specification conveys with reasonable clarity that Appellants were in possession of the invention now claimed. The rejection for lack of written description is reversed.

4. Enablement

The examiner rejected the claims as nonenabled because

> if the term 'functional immune system' is interpreted as meaning possessing all normal immune functions, no tumor bearing patient would actually have a 'functional immune system' because they possess tumors which are generally capable of generating antitumor immune responses, yet the patient has not been able to utilize such responses to eliminate the tumor. . . . Thus, it would not be possible to practice the claimed method because the claimed method stipulates that the patient have a 'functional immune system' yet tumor bearing patients by definition lack a 'functional immune system'.

Examiner's Answer, pages 11 -12

The examiner's rejection depends on a claim construction that would classify an immune system as "nonfunctional" if it failed to prevent the development of a tumor in the patient. However, as we have construed the claim language, a "functional immune system" is not limited to immune systems that function perfectly or that prevent completely the development of infections or tumors. A "functional immune system" simply means an immune system that mounts a humoral and/or cellular immune response to foreign antigens. The examiner has provided no evidence or scientific reasoning to show that, so

construed, the claimed method is not enabled. We therefore reverse the rejection for nonenablement.

Summary

Read in light of the specification, the claim language is not indefinite, and the claims are both adequately described and enabled by the specification. We therefore reverse the rejections under the first and second paragraphs of 35 U.S.C. § 112.

REVERSED

Sherman D. Winters Administrative Patent Judge	)
	) BOARD OF PATENT
Demetra J. Mills Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
Eric Grimes Administrative Patent Judge	)

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